

### **REMARKS**

Claim 138 has been amended. Support for the claim amendments may be found throughout the specification and in the claims as originally filed. Applicants respectfully request the consideration of the species FveR27A in amended claim 138 once the search for the elected species Der p 2 and FveT29A is complete.

Claims 170-172 have been cancelled without prejudice. Applicants reserve the right to pursue the subject matter of those claims in a continuing or divisional application.

Claims 138 and 173-179 are pending.

### **CLAIM REJECTIONS**

#### ***Rejection of claims under 35 U.S.C. § 112, second paragraph***

The Examiner has rejected claims 138 and 173-179 under 35 U.S.C. § 112, second paragraph as being indefinite. See Office Action at p. 2. Claims 173-179 depend from independent claim 138.

The Examiner has pointed out that the claims are drawn to SEQ ID NO: 1 which is an oligonucleotide. See Office Action at p. 3. Applicants have amended claim 138 to correctly recite SEQ ID NO: 6 which is a polypeptide sequence.

Applicants respectfully request the withdrawal of this rejection.

#### ***Rejection of claims under 35 U.S.C. § 112, first paragraph***

##### ***Enablement***

The Examiner has rejected claims 138 and 173-179 under 35 U.S.C. § 112, first paragraph, for lack of enablement." See Office Action at p. 3. Claims 173-179 depend from independent claim 138.

The Examiner's rejection is based on the fact that "the amendment to claim 138 to include SEQ ID NO: 1 changes the scope of the claims to encompass[] subject matter that is not a method of producing a polypeptide, contrary to Applicant's assertion." See Office Action at p. 4. As such, the Examiner concludes that "the specification has not adequately disclosed a method for producing the recited polypeptide comprising an oligonucleotide of SEQ ID NO: 1." Id.

Claim 138 has been amended to correct the typographical error and now correctly recites a method for producing a polypeptide capable of stimulating an immune response against a

molecule, the method including (a) identifying a molecule against which the stimulation of the immune response is desired, the molecule including a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2); and (b) forming a fusion protein by joining the molecule as a first portion thereof with a second portion being an Fve polypeptide having a sequence shown as **SEQ ID NO: 6** and including a mutation selected from the group including a mutation from R to A at position 27 of that sequence (R27A) and a mutation from T to A at position 29 of that sequence (T29A).

SEQ ID NO: 6 is a polypeptide sequence of the Fve polypeptide and the polypeptides recited in claim 138 correspond respectively to SEQ ID NOs:44 and 46, which the Examiner acknowledges as being enabled by the specification. See Office Action at p. 3. The specification at Examples 13 at page 117 describes the construction of each of the fusion proteins specified in claim 138. A schematic showing fusion proteins, which includes as first portion Der p 2 and second portions FveR27A or FveT29A is shown in Figure 16. Figure 17 describes expression of allergen-Fve fusion proteins, while Figures 18, 19, 21, 22, 23 show various results obtained and showing the characteristics of allergen-Fve fusion proteins. These are described in detail at Example 17.

It is clear from the above that the specification describes the invention in sufficient detail to enable a person skilled in the art to make the invention. Applicants therefore submit that claim 138 and dependent claims are sufficiently enabled by the specification as filed. Applicants respectfully request reconsideration and the withdrawal of this rejection.

### ***Written Description***

The Examiner has rejected claims 138 and 173-179 under 35 U.S.C. § 112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." See Office Action at p.5. Claims 173-179 depend from independent claim 138.

The Examiner has acknowledged that "Applicant is in possession of: a method for producing the fusion proteins of SEQ ID NO: 44 and 46." *Id.* The Examiner however, states that "Applicant is not in possession of : a method for producing a polypeptide comprising the oligonucleotide of SEQ ID NO: 1." See Office Action at p. 5.

Applicants have amended claim 138 to correct the typographical error. Claim 138 now correctly recites SEQ ID NO: 6 which a polypeptide sequence. As previously pointed out, the specification at Example 13 at page 117 describes the construction of each of the fusion proteins specified in claim 138. Figure 16 shows fusion proteins, which includes as first portion Der p 2 and second portions FveR27A or FveT29A. Figure 17 describes expression of allergen-Fve fusion proteins, while Figures 18-23 show various results obtained and showing the characteristics of allergen-Fve fusion proteins. These figures are described in detail at Example 17.

Accordingly, the specification sufficiently describes the claimed invention in full, clear, concise and exact terms and satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Thus Applicants respectfully request reconsideration and withdrawal of this rejection with respect to claim 138 and dependent claims thereof.

#### ***New Matter Rejection***

The Examiner has further rejected claims 138 and 173-179 for containing new matter. See Office Action at p. 6-7. Claims 173-179 depend from independent claim 138.

Specifically, the Examiner contends that "Applicant's amendment does not point to the specification for support for the newly added limitation of an 'Fve polypeptide having a sequence shown as SEQ ID NO: 1 ...." See Office Action at p. 7.

Applicants have amended claim 138 to correct the typographical error in the SEQ ID number. Claim 138 now correctly recites an "Fve polypeptide having a sequence shown as SEQ ID NO: 6 ...." Support for this amendment may be found at, for example, the claims as originally filed and throughout the specification.

Applicants respectfully request reconsideration and withdrawal of this new matter rejection.

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**CONCLUSION**

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims now pending are in condition for allowance. Should any further fees be required by the present Reply, the Commissioner is hereby authorized to charge Deposit Account **19-4293**.

Respectfully submitted,

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